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07-06-04

1614 IPW

| | |
|---------------------------------|----------------------|
| DATE | 6-25-04 |
| APPLICATION NUMBER | 10/084,391 |
| RESPONSE TO OFFICE ACTION DATED | 3-25-04 |
| FIRST NAMED APPLICANT | Gregory Gene Steiner |
| EXAMINER | Rebecca Cook |
| ENCLOSED | |

1. RESPONSE TO OFFICE LETTER MAILED 3-25-04
2. COPY OF OFFICE LETTER OF 3-25-04
3. PETITION FOR EXTENSION OF TIME
4. REQUEST FOR STATUS CHECK
5. RESPONSE TO OFFICE LETTER OF 6-05-03 DATED 7-19-03
6. OFFICE LETTER 2-7-03
7. RESPONSE TO OFFICE LETTER 2-7-03 DATED 3-1-03



RESPONSE TO OFFICE LETTER 3-25-04

I received a Notice of Abandonment dated 3-25-04 due to applicant's failure to timely file a proper reply to the office letter mailed 2-7-03. However, I responded to the office letter dated 2-7-03 on 3-01-03 and filed on 3-04-03. I received an office letter mailed 6-05-03 with a notice of noncompliant amendment. I replied to this notice on 7-21-03. I did not hear a response to my reply of 7-21-03 and because I was assigned a new examiner who could not locate my file I faxed a REQUEST FOR STATUS CHECK ON 11-13-04. I received a notice that I had late filed my reply to the office letter dated 2-7-03 with a notice that I was required to pay for a one month extension. Although I did not think I filed any reply late I paid the one month extension on 2-23-04 in order to keep the process moving. I have reviewed the notice of abandonment with Mr. Dixon and he found all papers in order and could find no reason for abandonment. Under 37 CFR 1.181 please repeal the notice of abandonment and send the application to examiner Rebecca Cook for continued processing.

Sincerely,



Dr. Gregory Gene Steiner

590 Farrington Hwy., #524 Suite 132
Kapolei, Hawaii, 96707
PHONE 808 689 3130 or 949 306 9491



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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/084,391 | 02/26/2002 | Gregory Gene Steiner | | 8379 |

7590 03/25/2004
Gregory Gene Steiner
1676 Ala Moana Blvd. #104
Honolulu, HI 96815



EXAMINER

COOK, REBECCA

ART UNIT PAPER NUMBER

1614

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Patman

| | | |
|--------------------------------------|--------------------------------------|-----------------------|
| <p>1 JUL 02 2004 ent</p> | <p>Application No. 0/084,391</p> | <p>Ap S A</p> |
| <p>PATENT & TRADEMARK OFFICE</p> | <p>Examiner Rebecca Cook</p> | <p>1</p> |

Notice of Abandonment

Application No.

Applicant(s)

STEINER, GREGORY GENE

Examiner

Art Unit

Rebecca Cook

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 2/7/03.
 - (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
 - (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
 - (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
 - (d) ☒ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
 - (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
 - (b) ☐ The submitted fee of \$_____ is insufficient. A balance of \$_____ is due.
The issue fee required by 37 CFR 1.18 is \$_____. The publication fee, if required by 37 CFR 1.18(d), is \$_____.
 - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
 - (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
 - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:

571 2726571 Rebecca Cook

Rebecca Cook
Primary Examiner
Art Unit: 1614

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.



PTO/SB/22 (08-03)

Approved for use through 7/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| | | | |
|---|--|---------------------------|--|
| PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) | | Docket Number (Optional) | |
| In re Application of <u>GREGORY G. STEINER</u> | | | |
| Application Number <u>10/084,391</u> | | Filed <u>Feb 26, 2002</u> | |
| For | | | |
| Art Unit <u>1614</u> | | Examiner | |

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

- ☒ One month (37 CFR 1.17(a)(1)) \$ 110⁰⁰
- ☐ Two months (37 CFR 1.17(a)(2)) \$ _____
- ☐ Three months (37 CFR 1.17(a)(3)) \$ _____
- ☐ Four months (37 CFR 1.17(a)(4)) \$ _____
- ☐ Five months (37 CFR 1.17(a)(5)) \$ _____

☒ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee amount shown above is reduced by one-half, and the resulting fee is: \$ 55⁰⁰.

☒ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number _____.

I have enclosed a duplicate copy of this sheet.

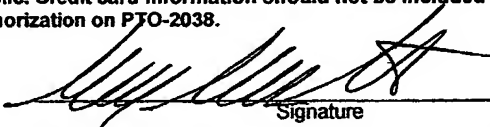
I am the ☒ applicant/inventor.

- ☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).
- ☐ attorney or agent of record. Registration Number _____
- ☐ attorney or agent under 37 CFR 1.34(a).
Registration number if acting under 37 CFR 1.34(a) _____

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

2-23-04
Date

949 306 9491
Telephone Number


Signature
GREGORY G. STEINER
Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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Allyson VA

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G STEINER
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Box #132

STEINER HEALTHCARE LLC
565 AVE SEVILLA UNIT D (949) 306-9491
LAGUNA HILLS, CA 92653

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Start time : Nov-13 12:18pm
End time : Nov-13 12:21pm
Pages sent : 015
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To: United States Patent and Trademark Office
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REQUEST FOR STATUS CHECK

Please check the status of patent application #10/084,391. Attached is the last communication with your office including a copy of the express mail receipt. Please contact me by phone at 949 306 9491 or email at gsteinen@yahoo.com.

Sincerely,

Gregory Gene Steiner
1676 Ala Moana Blvd. #104
Honolulu, Hawaii 96815

Rebecca Cook

5712720571

To: United States Patent and Trademark Office

Fax: 703 308 4242



REQUEST FOR STATUS CHECK

Please check the status of patent application #10/084,391. Attached is the last communication with your office including a copy of the express mail receipt. Please contact me by phone at 949 306 9491 or email at ggsteiner@yahoo.com.

Sincerely,

Gregory Gene Steiner
1676 Ala Moana Blvd. #104
Honolulu, Hawaii 96815



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G. STEINER
1676 ala Moana #104
Honolulu HI
96815

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DATE

07/19/2003

APPLICATION NUMBER

10/084,391

RESPONSE TO OFFICE ACTION DATED 06/05/2003

FIRST NAMED APPLICANT

Gregory Gene Steiner

EXAMINER

Jerome D Goldberg

ART UNIT

1614

ENCLOSED

1. Notice of Non-Compliant Amendment
2. Copy of previously filed amendment
3. Clean version of the replacement section [0016]
4. Clean version of the replacement Claim 1

The Notice of Non-Compliant Amendment was mailed to my previous address. The USPTO has been noticed that my address has changed. Please send all future mailings to

Gregory Gene Steiner
1676 Ala Moana Blvd. #104
Honolulu, HI 96815



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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/084,391 | 02/26/2002 | Gregory Gene Steiner | | 8379 |

7590
Gregory Gene Steiner
P O Box 61515
Honolulu, HI 96839

06/05/2003



| |
|----------|
| EXAMINER |
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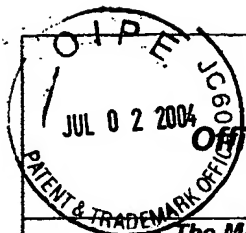
GOLDBERG, JEROME D

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1614

DATE MAILED: 06/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary

Application No.

10/084,391

Applicant(s)

STEINER, GREGORY GENE

Examiner

Jerome D Goldberg

Art Unit

1614

The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- ☐ Interview Summary (PTO-413) Paper No(s). ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

The U.S. patents are cited to complete the record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Volz et al. reference.

The Volz et al. Reference having an effective date of January 1, 1997 teaches applicant's Kavain as having therapeutic use in patients (see TX, line 8) and shows oral administration at 270-330mg/day for 22/weeks (TX lines 8-20).

The instant claims are directed to preventing a condition which would read on a normal host. Therefore, one skilled in this art would find ample motivation from the prior art supra to employ a known pharmaceutical kavain for preventing a condition with a reasonable expectation that said compound would be effective. Moreover, in the 24 weeks of treatment there would be a time wherein the patient was ^Ucared and still received the pharmaceutical.

Changing the mammal to a "mammal in need thereof" would overcome this rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by the Hapka et al. reference.

The Hapka et al reference teaches toxicological studies of kavain in mammals (see ST line 3 and RN, line 1) clearly, toxicity studies would be administering to a normal mammal. Changing the mammal to a "mammal in need thereof" would overcome this rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-6 of copending Application No. 09/ 792,898. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed applicant's compound for chemopreventing cancer while the parent application is directed to a reduced scope of the compounds for chemopreventing cancer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerome Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday 9:00 A.M - 3:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

→ 571 272 1600
0507

Goldberg/T.G.D.
February 3, 2003

JEROME D. GOLDBERG
PRIMARY EXAMINER

Rebecca Cox
Margaret Severo
→ 571 272
0511



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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| EXAMINER |
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| | |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

DATE MAILED:

Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment filed on 3-4-03 is considered non-compliant because it has not been submitted in the format required under 37 CFR 1.121, as amended on September 8, 2000 (see 65 Fed. Reg. 54603, Sept. 8, 2000, and 1238 O.G. 77, Sept. 19, 2000).

- ☒ 1. The amendment does not include a clean version of the replacement paragraph(s)/section(s). 37 CFR 1.121(b)(1)(ii).
- ☐ 2. The amendment does not include a marked-up version of the replacement paragraph(s)/section(s). 37 CFR 1.121(b)(1)(iii).
- ☐ 3. The amendment does not include a clean version of the amended claim(s). 37 CFR 1.121(c)(1)(i).
- ☐ 4. The amendment does not include a marked-up version of the amended claim(s). 37 CFR 1.121(c)(1)(ii).
- ☐ 5. Other _____
- ☐ **PRELIMINARY AMENDMENT:** Unless applicant re-submits the preliminary amendment in compliance with revised 37 CFR 1.121 within ONE MONTH of the mail date of this letter, examination on the merits may commence without entry of the originally proposed preliminary amendment. This notice is not an action under 35 U.S.C. 132, and this ONE MONTH time limit is not extendable.
- ☒ **AMENDMENT AFTER NON-FINAL ACTION:** Since the above mentioned reply appears to be *bona fide*, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

For your convenience, attached to this correspondence is a copy of an informational flyer (MPEP Bookmark Bulletin on "Simplified Amendment Practice").

Mr. P. P. P.
Legal Instruments Examiner